IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA

KYLE M. SWISHER.	)	
	)	
Plaintiff,	)	
vs.	)	NO. CIV-14-0028-HE
	)	
STRYKER CORPORATION,	)	
CORIN GROUP PLC, and	)	
CORIN USA LIMITED,	)	
	)	
Defendants.	)	

ORDER

Defendants Corin Group PLC and Corin USA Limited (collectively "Corin" or "defendants") have moved to exclude the testimony of Charles W. Powell on Daubert grounds.[1] The court held a hearing on the motion on January 25, 2016.

The general standards for a Daubert challenge to expert testimony are well established. "In accord with [Rule 702], the Supreme Court has determined that the [trial judge] 'must ensure that any and all scientific testimony or evidence is not only relevant, but reliable.'" Bitler v. A.O. Smith Corp., 400 F.3d 1227, 1232 (10th Cir. 2004) (quoting Daubert, 509 U.S. at 589). This gatekeeper function applies to all expert testimony, not merely to that deemed to be "scientific" in nature. Kumho Tire Co. Ltd. v. Carmichael, 526 U.S. 137, 147-49 (1999). Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education,

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[1] *Daubert v. Merrill Dow Pharm., Inc., 509 U.S. 579 (1993). See also Fed.R.Evid. 702, which substantially incorporates the principles of Daubert.*

> may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

In deciding the admissibility of expert testimony, the court must determine whether the expert is proposing to testify to scientific or other specialized knowledge which will assist the trier of fact in understanding or determining a fact in issue. Daubert, 509 U.S. at 592. The court first determines whether the proposed expert "is qualified by 'knowledge, skill, experience, training, or education' to render an opinion." United States v. Nacchio, 555 F.3d 1234, 1241 (10th Cir. 2009) (en banc) (quoting Fed.R.Evid. 702). Further, to be qualified, the expert's knowledge, skill, experience, training or education must be relevant to the facts or matters at issue. Ralston v. Smith & Nephew Richards Inc., 275 F.3d 965, 969 (10th Cir. 2001) The court then conducts a further two-part inquiry, determining first if the expert's proffered testimony has "'a reliable basis in the knowledge and experience of his [or her] discipline.'" Bitler, 400 F.3d at 1232-33 (quoting Daubert, 509 U.S. at 592). In making this determination, the district court must decide whether the reasoning or methodology underlying the testimony is scientifically valid. *Id.* at 1233. Second, the district court must inquire "into whether proposed testimony is sufficiently 'relevant to the task at hand.'" *Id.* at 1234 (quoting Daubert, 509 U.S. at 597). Is there an appropriate "fit" between the evidence offered and the material issue to which it is directed?

The expert opinions sought to be offered by Mr. Powell were stated in his expert report [Doc. #118-2], as supplemented by an affidavit [Doc. #118-1] submitted by him after

defendants' Daubert motion was filed and as clarified by his testimony at the hearing.[2] The opinions are not readily distilled into a discrete, numbered listing. However, those most pertinent to the disposition of this motion may be summarized as follows: (1) that the hip resurfacing components (the Cormet Hip Resurfacing System) implanted in the plaintiff, and later removed, reflected use of a heat treatment in their manufacture, (2) that the heat treatment effected a change in the microstructures of the components – specifically the reduction or elimination of the "discrete, large carbide characteristics" – which would otherwise have existed in the absence of the heat treatment, (3) that the materials used in the implant were required by the FDA to be compliant with the industry standard as provided in American Society for Testing and Minerals ("ASTM") F-75,[3] (4) that ASTM F-75 includes an inherent requirement that, to be compliant with the standard, the microstructures of the particular device must be consistent with those of devices which were not heat treated, (5) that the device implanted in plaintiff had microstructures different from those of a non-heat treated device (specifically, the change in the nature of the carbide characteristics) and were therefore non-compliant with ASTM F-75, (6) that these deviations from the ASTM standard caused increased wear to the components of the device, which in turn increased the amount of chromium and cobalt released into plaintiff's body, and (7) that these increased amounts

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[2]*Defendants sought to strike the affidavit as a "sham" affidavit inconsistent with the original report and on the basis it was not a timely disclosure. While the affidavit reflects a change of emphasis, if not of direction, the court concludes it does not so materially contradict the prior report as to warrant striking it as a sham.*

[3]*ASTM F-75 sets certain of the specifications and standards for devices like those of the Cormet system.*

caused plaintiff's medical or neurological problems.[4]

In their motion, defendants challenge Mr. Powell's qualifications to offer at least some of the opinions he identifies. They also essentially challenge the reliability and "fit" of others.

To the extent that Mr. Powell would testify to the composition of the particular devices, including their microstructures, he is plainly qualified to do so. He is a registered professional engineer with particular training and experience in metallurgical testing and analysis. He has regularly evaluated the physical aspects of material failures and the like. In light of this experience and training, the court concludes Mr. Powell is qualified to express the opinions identified as (1) and (2) above.

The others are more problematic. Certain of them essentially express opinions about the nature of the FDA review and approval process. Mr. Powell's prior experience and training are substantially in areas other than medical devices. The limited experience he does have with medical devices did not involve Class III devices such as the Cormet system. He has no experience or training with respect to the FDA approval process at issue here. He does not have the necessary expertise to express an expert opinion about the nature of the approval process or what the FDA may have viewed as complying, or not complying, with

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[4]*Mr. Powell's description at the hearing of his conclusions included reference to the impact on plaintiff and his condition. It is not clear that he views the reach of his expert opinion as going to that, or whether he was simply summarizing the ultimate consequence of his opinion after giving effect to the evidence of others which he expected to be offered. In any event, it is clear Mr. Powell, a metallurgist/engineer, is not qualified to opine on the impact of particular minerals or other substances in a person's body.*

the standards of ASTM F-75.[5] In particular, he does not have the expertise to identify those things that the FDA may have viewed as "inherent" in the ASTM standard. As a result, Mr. Powell lacks the necessary qualifications to express opinions such as (4) through (7).

The particular opinion of Mr. Powell that is central to plaintiff's case—that ASTM F-75 includes an inherent requirement of microstructures consistent with a non-heat-treated device—must be excluded for a further reason. There is no reliable basis for it. Mr. Powell acknowledged that the ASTM F-75 standard does not include any explicit requirements related to microstructures. The evidence at the hearing included testimony from persons with substantial experience in the FDA approval process for this type of device. That evidence persuades the court that the idea of "inherent" or "implied" requirements in a specification like ASTM F-75 is inconsistent with the nature of the standard. Further, the evidence established that the FDA views multiple types of hip resurfacing devices—both heat treated and non-heat treated—as complying with ASTM F-75. Finally, the language of ASTM F-75 itself (plaintiff's hearing exhibit 6) makes clear that it does not contemplate an "inherent" requirement that heat processes not change the microstructures of the device. Paragraph 5.1 of the standard states: "Final thermal processing for castings, if any, shall be specified by mutual agreement between the supplier and purchaser." So there is no question the FDA contemplated the use of heat treatment as an approved and available means of preparing this type of device. And while it may be theoretically possible to use a heat treatment on a device

[5]*His opinion that this device is subject to the specifications of ASTM F-75 is not disputed by defendants.*

without changing its microstructures, there is no suggestion the FDA expected that. Indeed, it seem fairly clear from the hearing testimony that changing the microstructures of the device was exactly what defendants had in mind with their manufacturing process, which fact the FDA plainly knew.[6]

ASTM F-75 also states (para. 8.3): "Metallography—The microstructural requirements and frequency of examinations shall be mutually agreed upon by the supplier and purchaser." In other words, the FDA was not setting the microstructural requirements for a device subject to ATSM F-75. Finally, and perhaps most pertinent to Mr. Powell's opinion of an "inherent" requirement, is paragraph X1.3 of the specification, which states:

> "Various heat treatments, including hot isostatic pressing, solution annealing, and sintering, may be used on cobalt-28 chromium-6 molybdenum alloy surgical implant castings. This specification is not intended to cover the effects of such processes. (Emphasis added).

The changes in the microstructures of the device are, of course, one of the "effects" of the heat treating process.

In short, Mr. Powell's theory is inventive, but it wholly lacks a reliable basis in light of the explicit nature of the ASTM F-75 standard and the nature of the process that it is a part of. His testimony directed to some "inherent" requirement of ASTM F-75, and those conclusions which flow from it, will be excluded.

Based on the foregoing, defendants' motion to exclude the testimony of Mr. Powell

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[6]*Other documentary evidence at the hearing made it very clear the FDA knew Corin would be using a heat treatment process in connection with the device.*

[Doc. #113] will be **GRANTED in PART** and **DENIED in PART**. The motion is **DENIED** insofar as Mr. Powell seeks to offer opinions substantially in the nature of (1) and (2) identified above, but is otherwise **GRANTED**. Defendants' motion to strike sham affidavits [Doc. #124] is **DENIED** insofar as the motion is directed to Mr. Powell's affidavit.

IT IS SO ORDERED.

Dated this 3rd day of February, 2016.

JOE HEATON
CHIEF U.S. DISTRICT JUDGE